COOK INCORPORATED
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JUL 2 9 2013

510(k) SUMMARY
Cook Turbo-Flo® HD Acute Hemodialysis Catheter
21 CFR §807.92
Date Prepared: July 15, 2013

Submitter Information:

Applicant: Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (800) 468-1379
Fax: (812) 332-0281

Contact: Sean Spence, RAC
Phone: 812-339-2235 x5127
Fax: 812-332-0281

Device Information:

Trade name:	Cook Turbo-Flo® HD Acute Hemodialysis Catheter
Common name:	Blood access device and accessories
Classification:	II
Regulation:	21 CFR §876.5540
Product Code:	MPB: catheter, hemodialysis, non-implanted

Predicate Device:

K993933 Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue®. A two-lumen, short-term access central venous hemodialysis catheter.

Device Description:

The Cook Turbo-Flo® HD Hemodialysis Catheters are short-term, 12 Fr., hydrophilically coated, radiopaque polyurethane central venous catheters with two independent, non-communicating lumens. Lengths of 15, 20 and 25 cm are available based on the anatomical needs of the patient.

Various components may be included that are associated with placement of the device.

Table 5-1: Set/Tray Components

Components		
Introducer Needles	Drapes	Antiseptics
Catheter Introducer Needle	Safety Components	Scalpels
Dilators	Suture	Local Anesthetic
Wire Guide	Syringes	Tubing
Needle Free Connector		

Intended Use:

a. The **Cook Turbo-Flo® HD Acute Hemodialysis Catheter** is intended for acute hemodialysis, apheresis and hemofiltration. It is intended for percutaneous insertion into the subclavian, jugular or femoral veins. The device is a short-term use catheter (less than 30 days).

Comparison to Predicates:

The proposed devices are substantially equivalent to the predicates in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, anatomical location, and method of sterilization.

Technological Characteristics:

The Cook Turbo-Flo® HD Acute Hemodialysis Catheters are central venous access catheters intended for patients requiring acute hemodialysis, apheresis, and/or hemofiltration. Design elements such as the dual non-communicating lumens and different points of lumen termination support the flow and minimize recirculation. The following tests were conducted to ensure reliable design and performance:

- Tensile
- Flow Rate
- Burst Pressures
- Liquid/Air Leakage
- Collapsibility
- Cyclic Bending
- Leakage following Clamp Cycling
- Recirculation Rate
- Biocompatibility
- Sterilization
- Performance following Aging

The results of these tests support a conclusion that the proposed Cook Turbo-Flo® HD Acute Hemodialysis Catheters are as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 29, 2013

Cook Incorporated
% Sean Spence
Regulatory Affairs Team Lead
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K122091
Trade/Device Name: Cook Turbo-Flo® HD Acute Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: July 15, 2013
Received: July 17, 2013

Dear Sean Spence,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine and ChloraPrep, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122091

Device Name: Cook Turbo-Flo® HD Acute Hemodialysis Catheter

Indications for Use:

The Cook Turbo-Flo® HD Acute Hemodialysis Catheter is intended for acute hemodialysis, apheresis and hemofiltration. It is intended for percutaneous insertion into the subclavian, jugular or femoral veins. The device is a short-term use catheter (less than 30 days).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S